

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0707029	(X3) Date Survey Completed 08/11/2021
Name of Provider or Supplier Whitfield County Health Department	Street Address, City, State 800 Professional Blvd, Dalton, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 11, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory records review and Nursing director's interview, the laboratory failed to record environmental conditions appropriately as required by Clinical Laboratory Improvement Amendment guidelines in Whitfield County Lab from 2019 to 2021. Findings include: 1. Temperature records review revealed room temperatures, humidity and refrigerator temperatures were out of range in 2019, 2020 and 2021 in Whitfield County Lab mainly because the Normal Ranges on top of the laboratory maintenance logs were in-correct. 2. An interview the County Nursing director on 08/11/ 2021 at approximately 12:30 PM in the review room confirmed temperatures and Humidity were out range in 2019, 2020 and 2021 due to Normal Range error on maintenance logs.</p>